



STATE OF NEW YORK DEPARTMENT OF HEALTH

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Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

February 23, 2005

Dear Colleague:

By now you have all become aware of the New York City recent case of HIV infection with multi drug resistance in a gay man with apparent rapid progression to AIDS. This letter provides you with the latest facts and important information in response to the New York City health department's health alert of February 11, 2005. Especially given the reaction to the announcement of this case in the general media, it is important to understand the facts of the case to alleviate any concerns based on incomplete information.

The index case involves a man who reported multiple, unprotected high-risk sexual contacts with other men often accompanied by the use of methamphetamine ("crystal meth"). This case is cause for concern because the man was infected with a variant of HIV-1 that is resistant to three of the four current classes of anti-HIV medications and his clinical course rapidly progressed to AIDS following a possible acute retroviral syndrome in November 2004. (A copy of the Health Alert is available at <http://www.ci.nyc.ny.us/html/doh/html/public/press05/press05.html>). An investigation of this case is now underway to determine: 1) if this represents a particularly virulent strain of HIV; 2) if other persons were infected with the strain; and 3) the possible extent of its spread. As of the date of this letter, no other persons infected with the same strain and same clinical course have been identified, nor is there any clear link between multi-drug resistance and increased virulence in this case.

The attached guideline identifies seven key areas that warrant special focus in the delivery of clinical care to individuals at risk for or with HIV infection. I urge you to review this information and to appropriately incorporate it in your practice.

While the investigation is underway, it is important to consider the lessons learned from this case and place it in the context of our multi-pronged response to the HIV/AIDS epidemic in New York. First and foremost, at this point, this case is the only one that we know of. Whatever the outcome of the investigation, this case provides us with the opportunity to reaffirm our approach to combating the virus and to redouble our efforts to provide comprehensive and effective prevention to all persons infected and affected by HIV. In so doing, we should be guided by our commitments to science-based approaches and to the public health principles that have stood us in good stead in the past, including counseling and testing, referral, supportive programs, and the steadfast protection of confidentiality. The effective use of data to guide programs, addressing all the barriers that impede prevention and care efforts, ensuring access to treatment and services, and involving affected communities in HIV programs, will also continue to be cornerstones of our approach.

We have made tremendous strides over the past decade -- since the highly active antiretroviral therapy was introduced -- in improving the health status and quality of life for many with HIV infection. However, we all know that treatment is not always successful. There are still too many deaths from HIV/AIDS, and new infections even in the presence of good prevention continue to occur at an unacceptable rate. Adherence to treatment will need continual reinforcement to promote effective treatment and optimal health for people with HIV, since it assures maximum benefit from therapy and can prevent resistance to HIV medications.

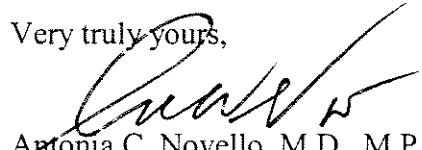
I also would like to urge all of you to take this time to clearly and comprehensively work together to address the devastating problem of HIV and drug use. Methamphetamine is the most recent of many drugs that are known to be associated with HIV transmission. This drug -- often called "crystal meth" -- is of particular concern because of its disinhibiting effects that often lead to unsafe sexual behaviors. Crystal meth use, is not limited to subpopulations of MSM/gay men, but it is also used by women and heterosexual men. It is imperative, therefore, that we strengthen our outreach and education about the potential dangers of this drug to all persons at risk and increase efforts to refer any individual at risk for care and treatment.

HIV is preventable. Statistics indicate, however, that over 40,000 individuals continue to be infected with HIV each year in the U.S. We know that many of these new infections occur in persons of color, women, adolescents, and men-who-have-sex-with-men (MSM)/gay men. Prevention messages and strategies need to be continually reinvented for the new generation and/or subpopulations that have not yet experienced the ravages of HIV. They need to heed the message of the importance of knowing one's HIV status. And they need as well to combat the idea that HIV is just another chronic disease that can be readily treated. In addition, people with HIV need to take responsibility for not transmitting infection to others. Some persons with HIV may not be aware that they may be placing their own health at risk of acquiring sexually transmitted and/or blood borne infections, including HIV superinfection, by continuing risky behavior. Today, complacency is our biggest enemy. We need to warn those we are trying to protect of the dangers associated with risky behaviors and help them find alternatives.

The New York State Department of Health will continue to work to assure that all individuals infected and affected with HIV live the healthiest, most productive lives possible. In doing so, we will continue to develop new programs and strategies for care and treatment.

The attached document is intended as a ready reference to assist you in helping your patients, your clients and your community. I thank you for your continued dedication to the fight against HIV.

Very truly yours,


 Antonia C. Novello, M.D., M.P.H., Dr.P.H.
 Commissioner
 New York State Department of Health

Attachment

Key Public Health Messages for HIV Clinicians

Case of 3-Drug Class Resistant HIV Infection in New York City

On February 11, 2005, the New York City Department of Health and Mental Hygiene (NYSDOHMH) released a Health Alert titled: **Primary 3-Drug-Class-Resistant HIV-1 Infection with rapid CD4+ T cell depletion and progression to AIDS in a New York City Man who has Sex with Men.** The case involves a man who has sex with men who used crystal methamphetamine and practiced unsafe insertive and receptive anal sex with multiple partners. This case raises public health concerns because:

- It appears that the man was infected with a strain of HIV-1 that is resistant to three of the (four) current classes of anti-HIV medications.
- The patient was diagnosed with symptoms of recent HIV infection in November 2004. His T-cell count rapidly dropped below 100 and he was diagnosed with AIDS by January 2005.

An investigation of this case is now underway to determine 1) if this represents a particularly virulent strain of HIV, 2) if other persons were infected with the strain, and 3) the possible extent of its spread. As of the date of this letter, no other persons infected with the same strain have been identified.

A copy of the Health Alert and a Fact Sheet developed by the NYSDOHMH are available at <http://www.ci.nyc.ny.us/html/doh/html/public/press05/press05.html>

This case brings to the forefront seven key areas that warrant special focus in the delivery of clinical care to individuals at risk for and with HIV infection:

I. Adherence to Treatment

It is well documented in the literature that non-adherence to HIV treatment regimens can result in an individual patient developing drug resistant strains of HIV. When drug resistant strains are present, one or more medication or classes of medications are not effective at controlling the virus. This means the patient has fewer treatment options and the virus is more difficult to treat. There have been concerns that if an individual develops a drug-resistant strain it can be passed to others during unsafe sex or needle sharing. The result of this could be that treatment options for these newly infected individuals will be limited. Several studies suggest that patients who are confident in the efficacy of their treatment are more likely to be adherent to therapy and their healthcare visits.

What Can HIV/AIDS Clinicians Do?

- Assess treatment readiness prior to initiation of therapy
- Explain the goals of therapy and the importance of adherence
- Assess potential or actual barriers that may impede adherence
- Review dosing schedule and any special instructions

- Anticipate and treat side effects
- Intensify interventions at times of decreased adherence
- Provide contact information if questions or concerns arise
- Review adherence at each patient encounter

Resources

For information about NYSDOH trainings, fact sheets and other education tools that help providers implement best practices in their facilities, visit the following DOH sponsored website: <http://www.hivguidelines.org>

Information for consumers about adherence and how to take each of the FDA-approved HIV drugs are available at: <http://www.health.state.ny.us/nysdoh/aids/edpdfs>. Or e-mail HIVPUBS@health.state.ny.us to request sample educational materials for consumers on HIV treatment adherence.

II. Partner Notification

By promoting testing of past and current contacts and educating these contacts about prevention of transmission to their subsequent sexual or needle sharing partners, partner notification can help prevent the spread of HIV. Partner notification is critical to helping reduce the spread of potentially drug-resistant strains of HIV or strains of HIV that may be associated with rapid progression to AIDS.

If you are involved in diagnosing new cases of HIV infection, HIV-related illness or AIDS, New York State law requires the reporting of:

- Positive HIV tests
- Diagnoses of HIV-related illness
- Viral load tests
- CD4 less than 500
- Clinically defined AIDS

What Can HIV/AIDS Clinicians Do?

- Discuss partner notification with all HIV infected patients on an ongoing basis
- Discuss latex barrier protection
- Discuss safe injection practices
- Reinforce behaviors that do not pose risk of HIV transmission
- Discuss drug and alcohol use and how they impair judgment
- Provide patient with options to support partner notification

Resources

The NYSDOH PartNer Assistance Program (PNAP) and the NCYDOHMH Contact Notification Assistance Program (CNAP) provide assistance regarding partner notification to people living with HIV and are available to provide consultation and

assistance to providers. Services are confidential, convenient, free, safe and tailored to the client's unique needs. For information about PNAP and CNAP visit: <http://www.health.state.ny.us/nysdoh/aids/docs/9300.pdf> or call the PartNer Assistance Program at 1-800-541-AIDS, 1-800-233-SIDA (for Spanish language) or CNAP at 1-888-792-1711 or 212-693-1419.

For information about NYSDOH trainings, fact sheets and other provider education tools that can help you implement best practices in your facility, visit the DOH website at: <http://www.health.state.ny.us/nysdoh/hiv aids/hivpartner/reportquest.htm>

III. Prevention with HIV Positive Patients

The Centers for Disease Control and Prevention estimates that between 850,000 and 950,000 individuals are living with HIV in the U.S. An important component of health and social support services for people living with HIV is ongoing education, support and interventions to help the individual avoid passing HIV to others. Prevention for people with HIV takes on even greater public health importance if highly virulent and/or drug resistant strains of HIV are present in a community.

What Can HIV/AIDS Clinicians Do?

- Initiate risk-taking behavior discussion in non-judgmental manner
- Discuss the importance of HIV prevention at each visit
- Determine methods the patient is using to prevent HIV transmission
- Reinforce positive prevention behaviors
- Emphasize HIV transmission can occur during unprotected sex even when viral loads are undetectable
- Discuss drug and alcohol use and how they impair judgment
- Refer to substance abuse treatment services as indicated

Resources

The New York State ***Criteria for the Medical Care of Adults with HIV Infection***: For a copy of these clinical guidelines visit www.hivguidelines.org

Two new trainings to assist health and human services provider in promoting HIV prevention with their HIV positive clients have been developed and will be available in early spring, 2005. For information about these two courses, ***Addressing Prevention with HIV Positive Clients*** and ***Addressing Prevention in HIV Case Management***, visit www.health.state.ny.us/nysdoh/aids/training.htm

IV. HIV Testing Among People Unaware of their HIV Status

The only way to know if an individual is infected with HIV is to get tested. Promoting HIV testing, especially among people who engage in high risk activities, is critical to identifying new cases, beginning the partner notification process and promoting access to health care and adherence services, when appropriate. Early identification of HIV, including strains that are drug resistant or that may result in rapid progression to AIDS, is critical to stemming the spread of the virus.

What Can HIV/AIDS Clinicians Do?

Encourage testing for all clients who have

- Had sex, anal, oral or vaginal, without using a latex condom.
- Had many sex partners.
- Had sex with someone who injects drugs.
- Shared syringes, needles, and other works to inject drugs of any kind (heroin, steroids, insulin, etc.)
- Shared needles for piercing or tattooing.
- Had a sexually transmitted disease.

Resources

There are numerous NYSDOH programs that promote HIV testing, including rapid HIV testing. For information about the "Two Good Reasons" campaign, Project Wave and other programs that promote testing visit:

<http://www.health.state.ny.us/nysdoh/aids/index.htm>

To find free, anonymous testing sites, with same day results, call 1-800-541-AIDS. Or, find sites in the New York State HIV Counseling and Testing Directory on line at: www.health.state.ny.us/nysdoh/aids, and click on the HIV testing link.

To refer patients to free, anonymous testing sites, with same day results, call 1-800-541-AIDS. Or, find sites in the NYS HIV Counseling and Testing Directory on line the above web link.

V. Resistance Testing for Newly Diagnosed Individuals

The emergence of drug resistance mutations during antiretroviral therapy results in virologic failure and limited therapeutic options for patients.

What Can HIV/AIDS Clinicians Do?

- Genotypic resistance testing should be performed before initiating treatment in ARV therapy-naïve patients to determine whether they were infected with drug-resistant virus.

- Resistance testing should be performed promptly in cases of virologic failure or incomplete viral suppression.
- Resistance testing should be performed while patients are still receiving therapy or have been off therapy for no more than 1 year.
- Expert advice should be sought for interpretation of resistance tests.

Resources

The NYSDOH Clinical Education Initiative (CEI) provides HIV Specialists who are available to discuss clinical management guidelines and provide information about resistance testing guidelines and the interpretation of results. To determine the CEI site in your region, visit www.hivguidelines.org

The New York State ***Criteria for the Medical Care of Adults with HIV Infection***: For a copy of these clinical guidelines visit www.hivguidelines.org

VI. Acute HIV Infection (AHI)

Diagnosing AHI infection, also called primary HIV infection, offers an opportunity to intervene when viral load is very high. At this stage, there is an increased likelihood of transmission if the individual engages in high risk behaviors. Even though there is no consensus about the long term benefits of antiretroviral treatment, potential benefits include reduction of viral load (which would reduce the likelihood of transmission), lower set point of viremia and preservation of certain immune functions.

Appropriate counseling can also be effective in changing behaviors during this period. Identifying, counseling and testing partners should be an essential part of the intervention.

What Can HIV/AIDS Clinicians Do?

- Maintain a high level of suspicion for AHI infection in all patients presenting with a compatible clinical syndrome.
- Immediately obtain appropriate laboratory testing (quantitative HIV RNA or p24 antigen).
- Confirmatory HIV antibody testing should be performed 3 to 6 weeks after diagnosis by HIV RNA testing.
- The potential benefits of therapy should be weighed against the potential risks, and the clinician and the patient should be aware that therapy of primary HIV infection is of unproven efficacy.

- Counsel the patient regarding potential limitations of HAART in acute primary infection, and individual decisions should be made only after weighing the risks and sequelae of therapy against the theoretical benefit of treatment.
- Once the clinician and patient have made the decision to use ARV therapy for primary HIV infection, treatment should be implemented with the goal of suppressing plasma HIV RNA levels to below detectable levels.

We need to learn more about the nature and management of AHI. There are clinical sites with research protocols for patients with AHI. These clinical trial sites usually have more resources and expertise available. For more information, please visit aidsinfo.nih.gov

Resources

The New York State ***Criteria for the Medical Care of Adults with HIV Infection***: For a copy of these clinical guidelines visit www.hivguidelines.org

The NYSDOH Clinical Education Initiative (CEI) provides HIV Specialists who are available to discuss clinical management guidelines. To determine the CEI site in your region, visit www.hivguidelines.org

VII. Crystal Methamphetamine (CM)

The use of the recreational drug crystal methamphetamine (MA) is expanding. The drug is used to initiate, enhance, and prolong sexual encounters. High risk behaviors associated with MA use may lead to increased HIV transmission. Clinicians should screen patients for MA use, encourage HIV testing among users who do not know their HIV status, and refer for specialized substance abuse treatment and counseling when needed.

Resources

Clinicians can access helpful information at the following sites

www.nida.nih.gov/Infobox/methamphetamine.html

www.health.org/

www.ci.nyc.ny.us

www.nyc.gov/html/doh/html/special/methamph.html